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10/551,772

10/03/2005

Ezio Bombardelli

2503-1173

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466 7590 02/09/2007
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EXAMINER

KATAKAM, SUDHAKAR

ART UNIT

PAPER NUMBER

1621

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
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3 MONTHS

02/09/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | | |
|------------------------------|-------------------------------|------------------------------------|--|
| Office Action Summary | Application No. 10/551,772 | Applicant(s) BOMBARDELLI ET AL. | |
| | Examiner Sudhakar Katakam | Art Unit 1621 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1-10.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 8-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-13 is/are rejected.
- 7) ☐ Claim(s) 1-7 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>10/03/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The examiner has considered applicant's Information Disclosure Statement of 10/03/2005. Please refer to the signed copies of the PTO-1449 forms attached herewith.

Specification

2. The first sentence of the specification should be corrected to reflect the fact that the instant application is a 371 of PCT/EP04/03055 filed on 03/23/2004.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: The structure of the formula Ia is wrong because the position 5 should be a hydrogen atom not a methyl group. Proper correction is needed for formula Ia and also its corresponding reactants, for example, formula II and IV. Please see figure 1 from **Naguib** (US 6,623,768) or **Galal et al** (J. Nat. Prod., 64, 399-400, 2001) for the structural formulas for ferutinine and jaeschkeanadiol.

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5. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear from the claim 6 whether applicants intended to delete "[[or 5]]" or that it is a part of the claim.

6. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear from the claim 13 whether the applicants intended to add word "acid" to the end of "p-pivaloyloxybenzoic" or that it is a part of the claim.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claim 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Tamemoto et al** (Phytochemistry, 763-767, 58, 2001).

The instant claim is drawn to a method of preparing a cosmetic or dermatological composition, which comprises adding an effective amount of *Ferula* spp extract or ferutinine to an acceptable excipient.

Tamemoto et al disclose a folk medicine for the treatment of skin diseases and wounds, which is tested the antibacterial activities of some isolated compounds from the *Ferula kuhistanica* and the one of the extracted compound is ferutinine [see Introduction and Results and discussion in page 763].

The difference between the instant application and **Tamemoto et al** is that in the instant application prepared a cosmetic or dermatological composition comprises ferutinine, which is extracted from *Ferula* spp, whereas **Tamemoto et al** teaches application of ferutinine, which is an extract of air-dried fruits of *Ferula kuhistanica*, for skin diseases.

The chemical constituents of genus *Ferula* have been studied by many groups and known in the art and several species of this genus have been used in folk medicine. *Ferula kuhistanica* has been used in Uzbekistan folk medicine to treat skin diseases and wounds [see **Tamemoto et al**, Introduction in page 763].

Therefore, in view of explicit teachings of **Tamemoto et al**, the examiner purports that it would have been obvious to a person of ordinary skill in the art, at the time of invention was made, extract the ferutinine from different sources of the genus *Ferula*, and make a dermatological composition and to apply for dermatological applications,

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with a reasonable expectation of success. Developing a composition with an acceptable excipients is known in the art and is a prima facie obvious because an ordinary artisan would be motivated to optimize the process in order to explore its applications to other skin related diseases.

Allowed Subject Matter

10. Claims 1-7 are objected to as being dependent upon a rejected base claims, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: the closest prior art (J.Org.Chem. USSR, 28, 10, 1992, 1666-1673) fails to teach or fairly suggest esterification of jaeschkenadiol with p-pivaloylbenzoic acid to make p-pivaloyferutinine and then its hydrolysis to make ferutinine.

Conclusion

11. No Claim is allowed.

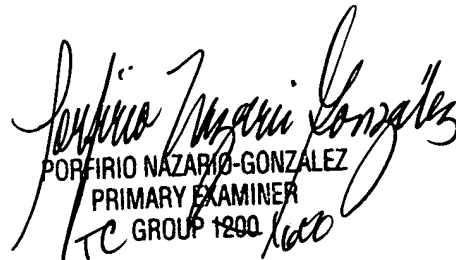
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhakar Katakam whose telephone number is 571-272-9929. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

S. Katakam


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